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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,880	06/01/2001	Jean-Louis Lalanne	446.001	6096

20311 7590 06/02/2004

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EXAMINER	
KATCHEVES, KONSTANTINA T	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/786,880	LALANNE ET AL.	
	Examiner	Art Unit	
	Konstantina Katcheves	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2003 and 10 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) *3-29 and 33-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 30-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *attached* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-43 are pending in the present application.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-8 and 30-32 in the papers filed 10 March 2004 and 05 November 2003 is acknowledged. It is noted that Applicant's representative, Michael Mercanti, agreed to the examination of claims 1-8 and 30-32 and the withdrawal from examination of claim 29 as being properly drawn to the invention of Group II. The traversal is on the ground(s) that the claims represent a single general invention. This is not found persuasive because the term "special technical features" is defined as meaning those technical features that define ***a contribution*** which each of the inventions considered as a whole, makes over the prior art see MPEP 1893.03(d), requiring the claimed inventions to be linked in the manner that they form a general inventive concept. In the instant case, having nucleic acids fragments thereof encoding a protein do not form a general inventive concept, because fragments of the claimed nucleic acids can be found in the art. See rejections below. Thus, the claimed inventions fail to disclose a shared technical feature, an inventive link between all the claims, and are not a contribution over the prior art.

The requirement is still deemed proper and is therefore made FINAL. Based on the election of SEQ ID NO:2 which encodes the CaNL256 gene, claims 3-8 have been withdrawn from consideration because they are drawn to genes corresponding to the non-elected sequences. Claims 3-29 and 33-43 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in the papers filed 10 March 2004 and 05 November 2003. Accordingly, claims 1, 2 and 30-32 insofar as they read on the gene CaNL256 encoded by SEQ ID NO:2 are currently under examination.

Abstract

The abstract of the disclosure is objected to because the word, "method" is misspelled. The species names such as *Candida albicans* should be italicized in abstract and the specification. Correction is required. See MPEP § 608.01(b).

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Pages 13, 29 and 31, for example, contain an embedded hyperlink. Applicant is required to delete these and any other embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Regarding the rules for the examination of biological deposits, 37 C.F.R. 1.809(d) states:

> For each deposit made pursuant to these regulations, the specification shall contain:
> (1) The accession number for the deposit;
> (2) The date of the deposit;
> (3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and
> (4) The name and address of the depository."

Page 4, recites plasmids deposited at DSMZ and their accession numbers. Deposits disclosed in a specification must include the address of the depository in addition to the accession numbers, date of deposit and name of depository.

Claim Objections

Claim 1 is objected to because of the following informalities: Claim 1 is drawn to non-elected subject matter. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 2 and 30-32 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

The claimed invention is drawn to polynucleotides of SEQ ID NO:2, functional fragments and homologs thereof.

The specification discloses the open reading frame of SEQ ID NO:2, gene CaNL256, from *Candida albicans*. The specification, as filed, does not provide any evidence or guidance suggesting the activity of the gene or that expression or lack of expression is associated with essential functions of the fungus. Although the specification prophetically asserts using the claimed nucleotide sequences in various protocols and recombinant technology including identification of antimycotics and essential gene of other fungal species, no evidence or guidance is provided that would suggest to a skilled artisan that there is any utility in using any of the nucleotide sequences in the asserted protocols since Applicant has not adequately described any specific activity for the gene encoded by the sequence of SEQ ID NO:2. Thereby, it is doubtful whether the nucleotide sequences can be used in any of Applicant's asserted utilities.

Additionally, the specification's lack of a specific and substantial asserted utility or a well established utility is further supported by the specification which is lacking in information regarding SEQ ID NO:2 and its function. At best, page 3 line 11-12, of the specification discloses that the sequences disclosed in the specification generally either encode dihydropteroate synthase (DHPS) or 7,8-dihydro-6-hydroxymethylpterin-pyrophosphokinase (HPPK) and presumably function as such. The specification does not specifically as the nexus between any of the disclosed sequences, including SEQ ID NO:2, and their respective functions either as DHPS or HPPK. The specification teaches the enzymatic pathways of each of these enzymes:

> Dihydropteroate synthetase (DHPS) catalyses the condensation of 6-hydroxmethyl-7,8-dihydropterin pyrophosphate to para-aminobenzoic acid to form 7,8- p dihydropteroate which corresponds to the second step in the three-step pathway leading from 6-hydroxymethyl-7,8-dihydropterin to 7,8-dihydrofolate. 7,8-dihydro-6- hydroxmethylpterin-pyrophosphokinase (HPPK) catalyzes the attachment of pyrophosphate to 6-hydroxymethyl-7,8-dihydropterin pyrophosphate to form to 6-hydroxmethyl-7,8-dihydropterin which corresponds to the first step in a three-step pathway leading to 7,8-dihydrofolate." See specification page 26, line 27 to page 27, line 1.

Pages 5-6 of the specification give some guidance as to how the determination of function was made by Applicants. These pages disclose that: "the first step is to identify said essential genes and starting from these thus identified genes, essential genes from other pathogenic mycetes can be identified. For practical purposes, 35 essential genes from S. cerevisiae are first identified and starting from them, essential genes from other pathogenic fungus, especially from Candida, are obtained." This disclosure suggests that the "essential genes" from *S. cervisiae* are first identified then by homology with these genes the essential genes from *Candida* are identified.

With regard to the specific elected sequence, SEQ ID NO:2, Example 1 on page 30 discloses homology between SEQ ID NO:2 and various enzymes. This example teaches that the gene called CaNL256 was obtained using a probe corresponding to a fragment of YNL256. The specification teaches that CaNL256 has 52% of nucleotides identical to YNL256 of *S. cerevisiae.*

The examiners search found a sequence match of SEQ ID NO:2 having 12% identity with a local similarity of 49.7% to YNL256 of *S. cerevisiae.* (Accession number SCYNL256W 1997). The deduced protein encoded by SEQ ID NO:2, SEQ ID NO: 3, had "40% amino acids identical with YNL256 of *S. cerevisiae* and 41% with FAS, folic acid synthase, of *Pneumocystis carinii.*" Additionally, Applicant discloses that two part of the CANL256 protein encoded by SEQ ID NO:2. These proteins are dihydropteroate synthase (DHPS) and 7,8-dihydro-6-hydroxymethylpterin-pyrophosphokinase (HPPK). This disclosure shows that homology is found between SEQ ID NO:2 and any one of DHPS, HPPK or folic acid synthase. These enzymes function very differently as disclosed by Applicant. DHPS promotes a condensation reaction and HPPK promotes phosphorylation. Given that the lack of significant homology and the fact that the "homologous" enzymes promote different reactions, SEQ ID NO:2 may function as a one of the disclosed enzymes or none of the disclosed enzymes. In other words, Applicant has not asserted a specific and substantial utility for SEQ ID NO:2.

Moreover, It is recognized in the art that assigning activity and function based on homology is unreliable and inexact. A protein's activity cannot be predicted based on primary structure alone. For example, Attwood teaches that "it is presumptuous to make functional assignments merely on the basis of some degree of similarity between sequences. . . . structure prediction methods are unreliable (and knowing structure does not inherently tell us its

function)." See Science Vol.290 2000 page 471, first column. Brenner also teaches that "without laboratory experiments to verify the computational methods and their expert analysis, it is impossible to know [the function of genes] for certain." See TIG Vol.15 no4 1999, page 132. Applicant has failed to engage in the analysis required to determine the function of SEQ ID NO:2 and therefore has not established a specific and substantial utility.

Therefor, as discussed above, neither the art not the specification as filed provides a specific and substantial asserted utility or a well established utility for SEQ ID NO:2; thereby, casting doubt on the utility of the claimed invention.

Claims 1, 2 and 30-32 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2 and 30-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement is established by 35 U.S.C. 112, first paragraph which states that the: "*specification* shall contain a written description of the invention. . .[emphasis added]." A specification must convey to one of skill in the art that "as of the filing date sought, [the inventor] was in possession of the invention." See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in "possession" of the invention claimed by describing the invention with all of its claimed limitations "by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention." See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

The instant claims are drawn to a polynucleotide encoding SEQ ID NO:2 and homologs and functional fragments thereof. These sequences have undefined modifications, which have certain activities or functions. The function of these sequences is not very clear from the specification. However, based on the brief disclosure on page 3, line 11-12, of the specification these sequences either encode dihydropteroate synthase or 7,8-dihydro-6-hydroxymethylpterin-pyrophosphokinase and presumable function as such.

These claims to polynucleotides of SEQ ID NO:2, homologs and functional fragments thereof are genus claims that encompass a wide array of molecules. The specification does not disclose any of these functional fragments or homologs, and the specification does not provide any teachings as to how the structures of these sequences relate to their presumed function. Thus, the specification does not describe the complete structure of a representative number of species or a representative number of species in terms of partial structure and relevant identifying characteristics. Absent any teachings and guidance as to the structure-function relationship of

this genus of sequences, the specification does not describe the claimed polynucleotide molecules in such full, clear, concise and exact terms so as to indicate that Applicant had possession of these molecules at the time of filing of the present application. Thus, the written description requirement has not been satisfied.

Claims 1, 2 and 30-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There is a logical disconnect between claims 1-2 and 30-32. Claim 1 recites a product. Claims 30-32 recite a product in the preamble, however, have method steps in the body of the claims referring to steps that are nowhere in claim 1. This inconsistency requires correction.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 30-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Accession number SCYNL256W.

The instant claims are drawn to a polynucleotide encoding SEQ ID NO:2 and homologs and fragments thereof.

Accession number SCYNL256W is drawn to a sequence having homology and encoding fragments of SEQ ID NO:2.

In view of the ambiguity of claims 30-32 set forth in the rejection under 35 U.S.C. 112, second, claims 30-32 may be product by process claims. The process by which a product is made must confer a patentable distinction to the product in order for the product to be considered patentable. In spite of the fact that the instant claims recite process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. In other words, SEQ ID NO:2 produced by the instant methods must be patentably distinct from SEQ ID NO:2 made from any other process. Since the prior art discloses a product which reasonably appears to be either identical with or only slightly different from the product claimed by Applicant in the instant claims, rejection is appropriate.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (571) 272-0768. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday 7:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Konstantina Katcheves
Group Art Unit: 1636